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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,757	08/21/2001	Jelle Wouter Slootstra	WE/P21526USOO	9985

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 04/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,757	SLOOTSTRA ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1 and 3-15 are pending and under examination.

Specification

The objection to the specification with respect to the abstract and arrangement of the specification has been obviated with the amendments to the disclosure.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific mimotope sequences obtained from the method using, specific library and steps, does not reasonably provide enablement for the broad scope of the method using any random library containing any amino acid building block that results in any type of amino acid combinations i.e., mimotope sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected,

to make and use the invention commensurate in scope with these claims for reasons advanced in the last Office action.

Response to Arguments

Applicants rely on the disclosure at page 4, line 6 up to page 5, line 10 and the Example as allegedly describing in detail a library of test sequences. The determination of the activity of the test sequences towards the receptor and the mimotope sequences for a variety of lead peptides.

In response, a review of the cited sections reveals nothing more than generalized statements. The Examples relate to describing a specific dodecamer using specific conditions for said 12-mer with antibody receptors. However, the claims are not limited to said Example. It covers a scope not taught in the specification. The claims recite for too numerous undefined variables. It claims any type of random library of test sequences. It does not define the kind, length and position modification of the test sequences, the activity, the building block, receptor and minicard. There is nothing in the specification that indicates that the 12-mer compounds utilizing specific conditions for said 12-mer could be applied to any types of random peptide of any length, building blocks, modifications and/or other unpredictable factors.

Applicants argue that the disclosure are enabling even if considerable amount of experimentation is involved, if it is merely routine.

In response, experimentation where predictability is merely speculative can hardly be considered routine. Applicants are working in a field i.e., library of peptides specifically, mimotope-antibody reaction that is notoriously known to be a highly unpredictable art. Even the used of presumably such known techniques as phage display, at times, do not produce the desired results. Phage display may not provide a true representation of the peptides in a library and at time results in unpredictable effect. This is recognized by no less than applicants e.g., at page 20, lines 10-15. Applicants discovered that the lead peptide, as a synthetic peptide, is not active (not in Elisa (pepscan or standard nor in solution). This is not unique. Often phage-peptides are only active as part of the phage-coat protein. In other formats they lose their activity. Phage library is only but one of the numerous libraries encompassed by the claimed scope and one of the numerous undefined variables or parameters of the broad claimed method. If applicants have encountered such difficulties, how much more for a skilled artisan, given only the limited guidance of specific components using the experimental conditions therein?

In biochemical reactions, unlike mechanical cases, prediction is very little, at times, almost nil. Attention is further directed to page 14, lines 31-35 of the disclosure. It recites "...the replacement analysis of the lead peptide CGCAAMNIRCYA resulted in the identification of building blocks that ***cannot be replaced by any other building blocks***..."

Accordingly, the specification is replete with general statements and a direction so limited to a specific method using specific components of the library and experimental conditions adapted for said specific library. The broad claimed invention is nothing more than an invitation to experiment.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

Response to Arguments

A. Applicants argue that the Office action recites that the terms "is favored at said position", "random library of test sequences composed of building blocks"; "certain position"; "next library of test sequences"; "selected building blocks" were definite (sic, indefinite). The term "molecule that is composed of a number of building block" is argued as defined at page 3, lines 21-31. Page 4, line 32-page 5, line 36 is argued to teach how a library can be provided or obtained.

In reply, page 3 fails to provide the metes and bounds of the claimed molecule, as it describes in general terms the compounds as generic as the claimed molecules. Also, reliance on the publication article, Sloostra (Molecular Diversity) is improper as this publication teaches the claimed and argued essential material i.e., making a library.

Applicants argue that claim 1 has been amended to recite additional steps and further clarify the original recited steps.

In reply, the addition of the single general step of "contacting with a receptor" does not obviate the rejection that the components of the methods do not have a characterizing or identifying feature that distinguishes one from the other. Neither does the rejection that the claimed steps are incomplete

for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01.

Applicants argue that the Official action objected (sic, rejected) the term "providing". Applicants believe that the term means to supply for use.

In response, applicants fail specifically point out where in the specification the supply for its use is described. Are these commercially available compounds that can be obtained from a supplier? If so, then applicants fail to recite the commercial source(s) for said library.

B). The rejection under this paragraph is moot in view of the cancellation of claim 2.

C). -K). The rejections of the various claims under these paragraphs have been overcome with the amendments to the claims and in part by applicants' arguments.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 3-15 are rejected under 35 U.S.C. 102(b) as being anticipated by any one of Pinilla et al (U.S. 5,556,762), Blake (U.S. 5,565,325) or applicants' disclosure of known prior art for reasons stated in the last Office action.

Response to Arguments

Applicants argue that none of the references discloses a method for determining a mimotope sequence wherein each test sequence is located on a minicard.

In reply, applicants' attention is directed Pinilla which cites the work by Geysen et al., which deals with methods for synthesizing peptides on a pepscan (minicard, as claimed) with specific sequences of amino acids and then using those peptides to identify reactions with various receptors. Reference is made to U.S. Pat. Nos. 4,708,871 and 4,833,092; P.C.T. Publications Nos. WO 84/03506 and WO 84/03564; Geysen et al., Proc. Natl. Acad. Sci. U.S.A., 81:3998-4002 (1984); Geysen et al., Proc. Natl. Acad. Sci. U.S.A., 82:178-182 (1985); Geysen et al., in Synthetic Peptides as Antigens, 130-149 (1986); Geysen et al., J. Immunol. Meth., 1.02:259-274 (1987); and Schoofs et al., J. Immunol., 140:611-616 (1988).

[It is of interest to note that the Examples in the specification do not recite a minicard. It recites a pepscan.

The only minicard used by applicants is described in the Dutch application, as stated in the specification. Without the Dutch application on file, it cannot be ascertained as to what exactly is a minicard].

Blake discloses the same process as claimed and also refers to the Geysen method.

Applicants discloses at page 12, line 27 up to page 13, line 7 that "in previous studies it was shown that such a strategy, without obtaining an unfavorable signal to noise ratio, can result in hundreds of binding peptides that resemble small linear or non-linear parts of the native epitope.....in addition to random mini pepscan libraries mimotopes can also be identified from standard pepscan libraries. These libraries contain all overlapping 12-mers....." The details of this method are evident from the now submitted Sloostra reference (Jrnl. of Molecular Recognition)(I), which uses the minicard. See further Sloostra (Molecular Diversity, 1995) reference cited in the Sloostra(I) which also describes the claimed method and uses said minicard.

No claim is allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571) 272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on . (571) 272-0811. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
April 17, 2004